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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:	Group Art Unit: 1648
BLONDER et al.	Examiner: Li, Bao Q.
Serial No.: 09/888,235	
Conf. No.: 8106	SUBMISSION OF REPLY BRIEF (37 C.F.R. § 41. 41)
Filed: June 22, 2001	
Atty. File No.: 42830-00234	
For: "DELIVERY VEHICLE COMPOSITION AND METHODS FOR DELIVERING ANTIGENS AND OTHER DRUGS"	EXPRESS MAIL LABEL NO. EV738038407US

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Submitted herewith is a Reply Brief pursuant to 37 C.F.R. § 41.41 following an Examiner's Answer dated July 12, 2006. It is believed that no fees are due in relation to the filing of the Reply Brief. However, if any fees are due, please debit such fees to Deposit Account No. 50-1419.

Respectfully submitted,

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By: _____

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Date: September 12, 2006

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Dear Sir:

This Reply Brief is filed in reply to an Examiner's Answer dated July 12, 2006 (hereinafter, "Examiner's Answer") to an Appeal Brief filed May 1, 2006 (hereinafter, "Appeal Brief") in relation to appeal of the referenced Application from claim rejections stated in an Office Action dated June 27, 2005 (hereinafter, "Appealed Office Action").

This Reply Brief includes the following appendices:

Appendix A – Claims, As Amended By Amendments Entered After Commencement Of Appeal.

REAL PARTY IN INTEREST

The real party in interest remains as RxKinetix, Inc, a Delaware corporation, assignee of record of the Application.

RELATED APPEALS AND INTERFERENCES

None.

STATUS OF CLAIMS

In the Examiner's Answer, the Examiner acknowledged entry of claim amendments filed on June 20, 2005 and April 28, 2006 after filing a Notice Of Appeal and prior to filing the Appeal Brief, amending Claims 148 and 149 and canceling Claims 150-197, and the Examiner withdrew grounds for rejection under 35 U.S.C. § 102(b) and under 35 U.S.C. § 112, first paragraph. The listing of the claims presented in Appendix A hereto include the above-referenced amendments, and the status of the claims is now as follows:

Claims 1, 4-7, 9-31, 33-37, 39-44, 148 and 149 are pending in the application, Claims 2, 3, 8, 32, 38, 45-147 and 150-197 having been cancelled. Claims 1, 4-7, 9-31, 33-37, 39-44, 148 and 149 are the subject of this appeal, and all of those claims are rejected under 35 U.S.C. §103(a).

STATUS OF AMENDMENTS

At the time of filing this Reply Brief, there are no outstanding amendments that have not been entered.

SUMMARY OF CLAIMED SUBJECT MATTER

The summary of the claimed subject matter remains as set forth in the Appeal Brief, noting only the amended preamble of Claims 148 and 149 (now properly stated to be compositions, and not methods) following the Examiner's entry of previously submitted amendments.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Following the Examiner's Answer, the following is the sole ground for rejection to be reviewed in this appeal (the other grounds for rejection having been withdrawn by the Examiner in the Examiner's Answer):

Ground 2: Rejection of Claims 1, 4-7, 9-31, 33-37, 39-44, 148 and 149 under 35 U.S.C. § 103(a) as obvious over EP 0 860 166 A1 by *Alonso et al.* (hereinafter "*Alonso et al.*") in view of US 5,607,691 by *Hale et al.* (hereinafter "*Hale et al.*") and US 5,300,295 by *Viegas et al.* (hereinafter "*Viegas et al.*")

EVIDENCE

The evidence relied upon remains as stated in Appendix B of the Appeal Brief.

ARGUMENTS IN REPLY TO EXAMINER'S ANSWER

The only ground of rejection now remaining for consideration as part of this appeal is the rejection under 35 U.S.C. §103(a) based on an assertion of obviousness over *Alonso et al.* in view of *Hale et al.* and *Viegas et al.*

From the Examiner's Answer, it now seems clear that in rejecting the claims for obviousness the Examiner is relying on those disclosures in *Alonso et al.* that relate to the composition of the so-called "formation medium" that is disclosed by *Alonso et al.* as a process medium in which the desired end product, drug-delivery nanoparticles, are made by precipitation. It is emphasized that it is critical to distinguish between the different teachings of *Alonso et al.* with respect to the composition and properties of that formation medium of *Alonso et al.* and the composition and properties of the drug-delivery nanoparticles of *Alonso et al.* For example, in the Examiner's Answer, the Examiner once again refers, without elaboration, to the subject matter of Claims 6-13 of *Alonso et al.* for the proposition that *Alonso et al.* teach a composition with a total weight of copolymer from 0% to 60%. As discussed in section I.D.2 of the arguments presented in the Appeal Brief, that compositional reference by *Alonso et al.* is to the composition of the drug-delivery nanoparticles and not to the formation medium that is used during processing to make those

nanoparticles. Also, as discussed below and more fully in the Appeal Brief, for obviousness analysis under 35 U.S.C. § 103(a) recognition of the different purposes of the formation medium disclosed by *Alonso et al.* and the reverse thermal gelling drug delivery compositions of *Viegas et al.* is critical to a determination of the teachings, suggestions and motivations to one of ordinary skill in the art considering those references.

Based on statements presented in the Examiner's Answer, the Examiner's position with respect to obviousness appears to be that *Alonso et al.* discloses a composition, albeit for the formation medium of *Alonso et al.*, that is so similar in compositional makeup to the compositional requirements of Claim 1, that the composition of Claim 1 is obvious, because one of ordinary skill in the art would bridge the differences between the formation medium of *Alonso et al.* and the composition of Claim 1 through determination of optimum or workable ranges by routine experimentation. This appears to be the position of the Examiner even though the formation medium is designed by *Alonso et al.* for use as a process medium in which drug-delivery nanoparticles are manufactured by precipitation and the composition of the invention as set forth in Claim 1 is designed for use of antigen delivery. *Viegas et al.* appears to be referred to by the Examiner primarily to show that the composition of the formation medium disclosed by *Alonso et al.* would inherently have the reverse thermal viscosity behavior, based on the reverse thermal gelling property of the drug delivery compositions described by *Viegas et al.* This apparent position of the Examiner is not tenable, for reasons already discussed in sections I and II of the arguments presented in the Appeal Brief concerning what *Alonso et al.* actually discloses in relation to the formation medium and how the disclosure of *Alonso et al.* would be viewed by one of ordinary skill in the art, with or without consideration also of the teachings of *Viegas et al.*. All of the discussion in section I of the arguments presented in the Appeal Brief are relevant to consideration of the sole remaining ground for rejection based on obviousness, even though that section was drafted primarily with respect to a now withdrawn novelty rejection based on *Alonso et al.*, because as discussed section I of the arguments presented in the Appeal Brief, *Alonso et al.* do not disclose a formation medium with the compositional make-up or the reverse thermal viscosity behavior recited in the appealed claims. However, because the Examiner has clarified in the Examiner's Answer some of the Examiner's

reasoning in maintaining the obviousness rejection, this Reply Brief is submitted to address particular assertions made in the Examiner's Answer.

The Examiner asserts that *Alonso et al.* shows a composition containing 0.14% chitosan, 0.014% diphtheria toxoid, 7% polyoxyethylene-polyoxypropylene block copolymer (PEO-PPO) and approximately 93% water, and on page 11 of the Examiner's Answer, the Examiner presents a table comparing this asserted composition of *Alonso et al.* to the compositional ranges for the adjuvant, antigen, polyoxyalkylene block copolymer and aqueous liquid, respectively, recited in appealed Claim 1. The Examiner asserts that the only component falling outside of the compositional ranges recited in Claim 1 is the aqueous liquid content, which the Examiner characterizes as a "minor proportional difference of 7-8% water," and which the Examiner asserts is not sufficient to demonstrate patentability over *Alonso et al.* absent some showing of criticality with respect to that difference in aqueous liquid content. Moreover, the Examiner reveals, on page 10 of the Examiner's Answer, the basis on which the Examiner has attempted to back-calculate the concentrations of components present in the asserted composition of *Alonso et al.*, because the Examiner recognizes that the asserted composition is not expressly disclosed by *Alonso et al.*

It is respectfully submitted that the composition asserted by the Examiner to be disclosed by *Alonso et al.* (containing 7% PEO-PPO and approximately 93% water) is not, in fact disclosed by *Alonso et al.*, and that the calculation basis relied upon by the Examiner is not supported by the disclosure of *Alonso et al.*

The Examiner's position appears to be that the asserted composition is inherent from the disclosure of data contained in Table 1, on page 6 of *Alonso et al.*, and particularly that such a composition is inherently disclosed by *Alonso et al.* based on the data presented in Table 1 for a chitosan/PEO-PPO ratio of 1/50 that *Alonso et al.* indicate resulted in preparation of nanoparticles having a size of 685 nm. To perform the calculation, the Examiner asserts that the formation medium used to prepare the 685 nm nanoparticles listed in Table 1 must have been made by *Alonso et al.* using a hypothetical formation medium constructed by the Examiner from a composite of ingredient concentrations selectively taken from Examles 3 and 5, and further modified by including a concentration of PEO-PPO that is back-calculated by the Examiner to achieve a ratio of chitosan to PEO-PPO of 1/50 (corresponding to the entry for that same ratio in Table 1). However, the asserted

connection between Examples 3 and 5 and generation by *Alonso et al.* of the data for the 1/50 ratio entry of Table 1 is based only on conjecture, because there is no disclosure in *Alonso et al.* that makes that connection, and conversely, the data presented by *Alonso et al.* in Table 1 confirms that the formation media used by *Alonso et al.* to generate the data of Table 1 was not generated using any of the five examples presented by *Alonso et al.*

As also discussed in section I.D.3 of the arguments presented in the Appeal Brief, the data presented by *Alonso et al.* in Table1 are not connected to the immediately proceeding examples presented by *Alonso et al.* Tables 1-5, which appear on pages 6 and 7 at the very end of the disclosure by *Alonso et al.*, are discussed by *Alonso et al.* in a much earlier section of the disclosure of *Alonso et al.* beginning at page 3, line 36 and extending through page 4, line 3, in a section of *Alonso et al.* generally concerning variables affecting properties of the desired drug-delivery nanoparticles. This section of the disclosure of *Alonso et al.* is presented prior to the examples, which commence on page 4, line 20, and there is no discussion anywhere in *Alonso et al.* that connects the data of Tables 1-5 to the examples. It appears as though Tables 1-5 of *Alonso et al.* were placed at the end of the disclosure for convenience, rather than to indicate a connection with the immediately preceding examples.

Moreover, a review of the data presented by *Alonso et al.* in Table 1, compared to the data disclosed by *Alonso et al.* in each of Examples 1-5, demonstrates that the data of Table 1 is not connected to those examples in a manner as asserted by the Examiner. In that regard, the following table has been constructed comparing nanoparticle size data shown in Table 1 of *Alonso et al.* with nanoparticle size data disclosed in Examples 1-5 of *Alonso et al.*, with the data for Examples 1-5 being shown opposite the chitosan/PEO-PPO ratio corresponding to those components disclosed by *Alonso et al.* to have been used in the those examples. Clearly, the data of Table 1 does not correspond to any of the examples, and there is no basis for the Examiner's assertion that the formation medium used to make the 685 nanometer particles disclosed in Table 1 is determinable by back-calculation.

Table: Comparison of *Alonso et al.* Nanoparticles of Table 1 with Examples 1-5

Chitosan/ PEO-PPO Ratio	Size of Nanoparticles Reported by *Alonso et al.* (nanometers)					
	Table 1 Nanoparticles	Example 1 Nanoparticles	Example 2 Nanoparticles	Example 3 Nanoparticles	Example 4 Nanoparticles	Example 5 Nanoparticles
1/0	275	402			245	245
1/2.5	283					
1/5	300		519			
1/25	430			741		
1/50	685					

As more fully discussed in the Appeal Brief, an assertion that a reference inherently discloses a particular composition must be based on a certainty, and not a mere possibility. Clearly, the Examiner's calculations purporting to show that *Alonso et al.* disclose a composition containing 7% PEO-PPO and approximately 93% water are not supported by the disclosure of *Alonso et al.*

Alonso et al. do not disclose a composition containing either from 5 to 33 weight percent polyoxyalkylene block copolymer or containing from 60 to 85 weight percent aqueous liquid, as is required of Claim 1. In fact, the highest PEO-PPO content and the lowest water content in a formation medium example disclosed by *Alonso et al.* is in Example 3, where the formation medium contained 3.5% PEO-PPO and approximately 96% water. Based on that formation medium composition disclosed in Example 3 of *Alonso et al.*, the PEO-PPO content of that formation medium is 30% smaller than the lowest permissible polyoxyalkylene block copolymer content recited in Claim 1, and the water content is about 13% larger than the highest permissible water content recited in Claim 1.

Moreover, the Examiner's assertion that differences in concentrations of components would be obvious to one of ordinary skill in the art based on routine experimentation for optimization is, respectfully, not correct. One of ordinary skill in the art considering the disclosure of *Alonso et al.*, would be motivated, if at all, to attempt to optimize the composition of the formation medium disclosed by *Alonso et al.* only for the purpose of the particular use disclosed by *Alonso et al.*, i.e. as a process medium for manufacture by precipitation drug-delivery nanoparticles containing chitosan and optionally also containing PEO-PPO polymer. One of ordinary skill in the art would have no motivation to attempt to optimize the concentrations of components in the formation medium to use

the formation medium for a different purpose that is not disclosed by *Alonso et al.*, i.e. to prepare a reverse thermal viscosity composition for antigen delivery as is recited in Claim 1.

The Examiner again cites to the case of *In re Aller*, 220 F.2d 454, 105 USPQ 232 (CCPA 1955) for the proposition: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." The situation presented here with respect to the subject matter of the appealed claims in relation to the disclosures of *Alonso et al.* is significantly different than the factual situation involved in *Aller*, and the reasoning of *Aller* simply is not applicable to this nonanalogous factual situation.

In *Aller*, the invention was a process for making phenol, the asserted prior art reference disclosed essentially the same process for making the same product, except that the invention used a somewhat lower temperature and higher concentration of one reactant, sulfuric acid. The purpose of the invention and the process of the prior art were the same, to make phenol. Although the inventors asserted that their process resulted in higher yields of phenol product, the Court noted that the improved results did not appear to be different in kind relevant to the prior art and that logically the improvements can flow equally well from changes in degree resulting from routine variation of temperature and acid concentration, and that there was no showing of anything critical about parameters of the process of the invention.

In contrast, the factual situation with the current application is significantly different than the factual situation presented in *Aller*. The claimed invention is a composition for delivery of an antigen, whereas the formation medium of *Alonso et al.* relied upon by the Examiner is not a composition for delivery of a drug, but rather is a composition used in processing to make the drug-delivery nanoparticles of *Alonso et al.* In *Aller*, the process of the invention and of the process of the prior art were essentially the same process practiced for the same purpose (i.e., to produce phenol), and the holding in *Aller* is premised on a recognition that minor changes in variables that result in a change of degree rather than kind would be within the scope of routine experimentation of one of ordinary skill of the art. In this situation, however, the claimed composition and the composition of the formation medium of *Alonso et al.* are not used for the same purpose, and the difference between the disclosed utility of the two compositions is indeed a fundamental difference in kind, and not just in degree (delivery of an antigen as opposed to process medium for precipitating drug-delivery

nanoparticles). Even though an example of the formation medium of *Alonso et al.* may coincidentally have compositional similarities to the composition recited in claim 1, it could hardly be considered routine experimentation to vary parameters of a process medium for the purpose of optimizing that process medium for the very different purpose of use as a composition for delivery of an antigen. The formation medium of *Alonso et al.* and the composition for delivery of an antigen recited in Claim 1 are clearly not analogous in the same way that the process of the invention and the process of the prior art were analogous in *Aller*.

Moreover, as discussed more fully in section I.D.4 of the arguments presented in the Appeal Brief, *Alonso et al.* do not, either expressly or inherently, disclose any composition, whether of the formation medium or otherwise, that contains reverse thermal viscosity behavior. The Examiner's apparent position that the formation medium compositions containing PEO-PPO polymer disclosed by *Alonso et al.* would necessarily contain reverse thermal viscosity behavior because of the nature of the PEO-PPO polymers is simply not correct. As discussed in the Appeal Brief, not every polyoxyalkylene block copolymer can be formulated with water to result in reverse thermal viscosity behavior, and even for those polyoxyalkylene block copolymers that can be formulated with water to exhibit reverse thermal viscosity behavior, not all proportions of polymer and water will exhibit such behavior. In that regard, attention is particularly directed to section 1.D.4 of the argument section of the Appeal Brief and the discussion presented there in relation to a paper by *Newman et al.* and a U.S. patent by *Cha et al.* concerning the same. In the Examiner's Answer, the Examiner has not considered the teachings noted in the Appeal Brief in relation to *Newman et al.* and *Cha et al.* confirming that not all PEO-PPO polymers, and not all concentrations of such polymers, would behave the same with respect to possessing reverse thermal viscosity behavior.

Instead, the Examiner cites to *Viegas et al.* for the apparent broad proposition that because *Viegas et al.* note that several polymers are known to be useful for imparting reverse thermal gelling behavior, that those polymers would necessarily have been the PEO-PPO polymers used by *Alonso et al.*, even though *Alonso et al.* do not disclose the particular polymers that are used, and even though the purpose for which the PEO-PPO polymer is used by *Alonso et al.* (inclusion in drug delivery nanoparticles) does not relate to reverse thermal viscosity behavior. Moreover, as discussed in more detail in section II.A of the arguments presented in the Appeal Brief, one of ordinary skill in the art

would not consider the teachings of *Alonso et al.* and *Viegas et al.* in combination because of their disparate subject matter, but even if, for the sake of argument, such a combination were considered, the combination would not make obvious the composition of Claim 1 or of the other appealed claims. In particular, there is no reason why one of ordinary skill in the art would consider modification of the formation medium of *Alonso et al.* to impart the reverse thermal gelling behavior of the drug delivery compositions of *Viegas et al.*, because the formation medium of *Alonso et al.* is not a drug delivery composition, but rather is a processing medium in which drug delivery nanoparticles are precipitated, whereas the disclosure of *Viegas et al.* is focused on the use of reverse thermal gelling compositions for the very different purpose of drug delivery.

Hale et al. is discussed in section II.B of the arguments presented in the Appeal Brief, and as discussed in the Appeal Brief, *Hale et al.* do not make up for the deficiencies of Alonso et al. and Viegas et al. The characterization of teachings of *Hale et al.* in the Examiner's Answer again combine out of context different portions of *Hale et al.* that are directed, respectively, to transdermal drug delivery by passive delivery transdermal patch (Examiner's citation to column 47 of *Hale et al.*) and to mucosal drug delivery to nasal and/or pulmonary membranes in an aerosol formulation (Examiner's citation to column 53, lines 12-25 of *Hale et al.*), which disparate teachings directed separately to fundamentally different drug delivery techniques do not lend themselves to selective extraction and recombination of elements, as suggested by the Examiner's analysis. In that regard, however, an inaccuracy is noted in section II.B.2 of the arguments presented in the Appeal Brief, where it is stated that the portion of *Hale et al.* cited by the Examiner in relation to "inhaler or nebulizer . . . mist . . . dry powder," etc. is included in excerpt (xxii) shown in the Appeal Brief. The correct reference should be to excerpt (xxiii) shown in the Appeal Brief. Nevertheless, the Examiner's Answer does not address the plainly disparate nature of the different teachings of *Hale et al.* concerning delivery by transdermal patch vs. nasal or pulmonary delivery with an aerosol formulation. The different formulation techniques disclosed for these very different administration routes are simply not combinable as suggested by the Examiner. Also, as discussed in the Appeal Brief, the references to "polyethylenes" identified by the Examiner in *Hale et al.* are not references to polyoxyalkylene block copolymers, as are recited Claim 1. On page 16 of the Examiner's Answer, the Examiner asserts, without elaboration, states: "*Hale et al.* also teach that synthetic copolymers

can be polyethylene copolymers." Even if this assertion were correct, it would not be a disclosure of the use by *Hale et al.* of polyoxyalkylene block copolymers, because polyethylene is not a polyoxyalkylene. Moreover, the Examiner's assertion with respect to copolymers of polyethylene is not correct. The Examiner specifically cites to column 47 of *Hale et al.* for the quoted assertion as to "polyethylene copolymers", but the only reference to "polyethylenes" in column 47 of *Hale et al.* is in line 53, and the reference is not in relation to copolymers of polyethylene. Rather, in a long listing of polymers for possible use as a permeable membrane material in a transdermal patch is disclosed by *Hale et al.*, which listing includes at column 47, lines 50-51 "polyurethane-polyether copolymers, polyethylenes, polyamides . . ." In that quoted portion of *Hale et al.*, "copolymers" clearly modifies "polyurethane-polyether" and not "polyethylenes."

Attention is also directed to the Rule 132 Declaration of Claire M. Coeshott (the "Coeshott Declaration") discussing mice study data relevant to claimed subject matter. The Coeshott Declaration notes the importance in particular of data showing that test compositions attained a faster antibody response than comparison compositions, and that this more rapid immunization is surprising. This faster antibody response would certainly be unexpected with respect to the teachings of *Alonso et al.*, (which is relied upon by the Examiner primarily in relation to the compositional make-up of a formation medium of *Alonso et al.* that is used in a nanoparticle manufacture process), the teachings of *Viegas et al.* (which is relied upon by the Examiner primarily in relation to reverse thermal gelling properties of certain compositions formulated with certain polymers) and the teachings of *Hale et al.* (which is relied upon by the Examiner primarily in relation to aerosol formulation).

CONCLUSION

The remaining ground of rejection based on 35 U.S.C. § 103(a) is unsupportable, and it is again respectfully requested that the rejection be reversed, and the application proceed to issuance.

Respectfully submitted,

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Date: September 12, 2006

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APPENDIX A
CLAIMS, AS AMENDED
BY AMENDMENTS ENTERED AFTER COMMENCEMENT OF APPEAL

1. (Appealed) A composition for delivery of an antigen for stimulation of an immune response when administered to a host, the composition comprising:

an antigen, a polyoxyalkylene block copolymer and an aqueous liquid;

the polyoxyalkylene block copolymer being biocompatible, not having toxic or injurious effects on biological function in the host when the composition is administered;

wherein, the composition is formulated with relative proportions of the liquid and the copolymer so that the copolymer interacts with the liquid to impart reverse thermal viscosity behavior to the composition, so that the viscosity of the composition increases when the temperature of the composition increases over some temperature range within 1 °C to 37 °C; and

wherein, the composition further comprises an additive enhancing the immune response when the composition is administered to the host, the additive being an adjuvant other than alum; and;

wherein, the liquid comprises from 60 weight percent to 85 weight percent of the composition, the antigen comprises from 0.0001 weight percent to 5 weight percent of the composition, the copolymer comprises from 5 weight percent to 33 weight percent of the composition and the additive comprises from 0.01 weight percent to 10.0 weight percent of the composition.

2. (Cancelled)

3. (Cancelled)

4. (Appealed) The composition of Claim 1, wherein the composition is in the form of a flowable medium when the composition is at a first temperature in the temperature range and the composition is in a gel form when the composition is at a second temperature in the temperature range, the second temperature being higher than the first temperature.

5. (Appealed) The composition of Claim 4, wherein the first temperature is in a range of from 1 °C to 20 °C.

6. (Appealed) The composition of Claim 4, wherein the first temperature is in a range of from 1 °C to 20 °C and the second temperature is in a range of from 25° C to 37 °C.

7. (Appealed) The composition of Claim 4, wherein the copolymer is substantially all dissolved in the liquid when the composition is at the first temperature, and at least a portion of the copolymer comes out of solution in the liquid when the temperature of the composition is raised from the first temperature to the second temperature.

8. (Cancelled)

9. (Appealed) The composition of Claim 1, wherein the polyoxyalkylene block copolymer comprises at least one block of a first polyoxyalkylene and at least one block of a second polyoxyalkylene.

10. (Appealed) The composition of Claim 9 wherein the first polyoxyalkylene is polyoxyethylene and the second polyoxyalkylene is polyoxypropylene.

11. (Appealed) The composition of Claim 10, wherein the polyoxyalkylene block copolymer has the formula:

$$HO(C_2H_4O)_b(C_3H_6O)_a(C_2H_4O)_bH$$

wherein a and each b are independently selected integers.

12. (Appealed) The composition of Claim 11, wherein the $(C_2H_4O)_b$ blocks together comprise at least 70 weight percent of the polyoxyalkylene block copolymer.

13. (Appealed) The composition of Claim 11 wherein a is between 15 and 80 and each b is independently between 50 and 150.

14. (Appealed) The composition of claim 10, wherein the polyoxyalkylene block copolymer has the formula:

$$H(OCH_2CH_2)_b(\overset{\displaystyle CH_3}{\overset{|}{O}}CHCH_2)_a(OCH_2CH_2)_bOH$$

wherein a is 20 to 80 and each b is independently 15 to 60.

15. (Appealed) The composition of Claim 1, wherein the antigen is selected from the group consisting of bacteria, protozoa, fungus, hookworm, virus and combinations thereof.

16. (Appealed) The composition of Claim 1, wherein the antigen is selected from the group consisting of tetanus toxoid, diphtheria toxoid, a non-pathogenic mutant of tetanus toxoid, a non-pathogenic mutant of diphtheria toxoid and combinations thereof.

17. (Appealed) The composition of Claim 1, wherein the antigen is from Bordatella pertussis.

18. (Appealed) The composition of Claim 1, wherein the antigen is from influenza virus.

19. (Appealed) The composition of Claim 1, wherein the antigen is from M. tuberculosis.

20. (Appealed) The composition of Claim 1, wherein the antigen immunizes against a childhood illness.

21. (Appealed) The composition of Claim 1, wherein the antigen is from rotavirus.

22. (Appealed) The composition of Claim 1, wherein the antigen is selected from the group consisting of a polysaccharide, a peptide mimetic of a polysaccharide, an antigen from Neisseria meningitiditis, an antigen from Streptococcus pneumoniae and combinations thereof.

23. (Appealed) The composition of Claim 1, wherein the antigen is from Epstein-Barr virus.

24. (Appealed) The composition of Claim 1, wherein the antigen is from Hepatitis C virus.

25. (Appealed) The composition of Claim 1, wherein the antigen is from HIV.

26. (Appealed) The composition of Claim 1, wherein the antigen comprises a molecule involved in a mammalian reproductive cycle.

27. (Appealed) The composition of Claim 1, wherein the antigen is HCG.

28. (Appealed) The composition of Claim 1, wherein the antigen is a tumor-specific antigen.

29. (Appealed) The composition of Claim 1, wherein the antigen is from a blood-borne pathogen.

30. (Appealed) The composition of Claim 1, wherein the antigen is a first antigen and the composition comprises a second antigen.

31. (Appealed) The composition of Claim 30, wherein the first antigen is selected from the group consisting of tetanus toxoid, a nonpathogenic mutant of tetanus toxoid and combinations thereof; and

the second antigen is selected from the group consisting of diphtheria toxoid, a nonpathogenic mutant of diphtheria toxoid and combinations thereof.

32. (Cancelled)

33. (Appealed) The composition of claim 1, wherein the adjuvant comprises dimethyl dioctadecyl ammonium bromide (DDA).

34. (Appealed) The composition of Claim 1, wherein the adjuvant comprises a CpG motif.

35. (Appealed) The composition of Claim 1, wherein the adjuvant comprises a cytokine.

36. (Appealed) The composition of claim 1, wherein the adjuvant comprises chitosan material.

37. (Appealed) The composition of claim 36, wherein the adjuvant comprises N,O-carboxymethyl chitosan.

38. (Cancelled)

39. (Appealed) The composition of Claim 1, wherein the composition is in the form of disperse droplets in a mist.

40. (Appealed) The composition of Claim 39, wherein the mist is produced by a nebulizer.

41. (Appealed) The composition of Claim 1, wherein the composition is contained within a nebulizer actuatable to produce a mist comprising dispersed droplets of the composition.

42. (Appealed) The composition of Claim 40, wherein the nebulizer is a nasal nebulizer.

43. (Appealed) The composition of claim 1, wherein the composition is contained within an injection device that is actuatable to administer the composition to the host by injection.

44. (Appealed) A method of packaging and storing the composition of claim 5, comprising placing the composition in a container when the composition is in the form of a flowable medium and, after the placing, raising the temperature of the composition in the container to convert the composition to the gel form for storage, wherein the gel form in the container can be converted back to the form of a flowable medium for administration to the host by lowering the temperature of the composition in the container.

45-147 (Cancelled)

148. (Appealed) The composition of Claim 1, wherein substantially all of the copolymer is dissolved in the liquid at some temperature within the temperature range.

149. (Appealed) The composition of Claim 1, wherein substantially all of the copolymer and the antigen are dissolved in the liquid at some temperature within the temperature range.

150-197. (Cancelled)